DERMANIC- niacinamide, inositol niacinate, niacin, chromium nicotinate, folic acid, hydroxocobalamin, ferrous cysteine glycinate and acetylcysteine zinc tablet
Allegis Pharmaceuticals, LLC

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

DermaNic
with Quadracin™
Plus CitraFolic®, AminoFerr®, and Zinc-NACx®

PRESCRIPTION (R_x)-DIETARY SUPPLEMENT
MULTIPHASIC TABLETS

PRODUCT CODE: ++28595-500-60

DESCRIPTION

DermaNIC™ is an orally administered, folate-containing prescription (R_x) dietary supplement for the clinical dietary management of suboptimal niacin and zinc levels associated with acne and/or acne therapy. **DermaNIC™** may be administered as adjunctive niacin-folate therapy to provide a protective effect in reducing the risk of hyperhomocysteinemia and/or pellegra in patients undergoing acne therapy or may be administered as monotherapy for patients who are in need of advanced niacin and zinc supplementation as determined by a licensed medical practitioner.[2,3,20,22,23] **DermaNIC™** is not a drug, but may be prescribed along with acne medications for concomitant care.[3] The ultimate goal of acne treatment is to address as many of the pathogenic factors of acne as possible while minimizing side effects.

DermaNIC™ is formulated with niacin and zinc, which support healthful methylation biochemistry and have anti-inflammatory effects via preservation of intracellular coenzyme homeostasis.[21] Furthermore, natural ingredients have been added to **DermaNIC™** that combine anti-inflammatory and antimicrobial properties along with inhibiting effects on sebum production.[22,24-26] Lastly, antibiotic use, which is common in acne patients, can lower the levels of B vitamins that are essential for methylation biochemistry.[18] Specifically, studies have shown that acne patients on isotretinoin therapy have decreased folate levels and increased levels of homocysteine.[19]

INGREDIENTS*:

Supplement Facts			
Serving Size: 1 Multiphasic Tablet		**Servings Per Container: 60**	
Amount Per Tablet			**% DV†**
Niacin (moiety) from Quadracin™‡		760 mg	3800%
moiety comprised of -	498 mg from nicotinamide (niacinamide) 260 mg from inositol nicotinate 1.5 mg from nicotinic acid 0.5 mg from chromium polynicotinate		
Folic Acid, USP as CitraFolic®§ [from controlled-release citrated-pteroylmonoglutamic acid]		500 mcg	125%
Cobalamin (hydroxocobalamin)		15 mcg	250%
Iron (elemental) as AminoFerr®¶ [from ferrous glycine cysteinate]		1.5 mg	8%
Zinc as Zinc-NACx®# [from zinc n-acetyl-l-cysteine]		20 mg	133%

Chromium [from chromium polynicotinate]	~70 mcg	58%
Inositol [from inositol nicotinate]	~68 mg	Þ
N-acetyl-l-cysteine [from zinc n-acetyl-l-cysteine]	49.5 mg	Þ

* *Daily Values not established for patients with unique nutritional needs who are in need of supplementation as directed by a licensed medical practitioner.*

† % Daily Value (DV) for Adults and Children Four or More Years of Age.

‡ ***Quadracin™*** *is a proprietary vitamin B_3 blend consisting of four forms of niacin - nicotinic acid, nicotinamide (niacinamide), chromium polynicotinate and inositol nicotinate.*

§ ***CitraFolic®*** *is a controlled-release form of folic acid that is pH-specific using citrates as buffers to achieve optimal absorption for targeted-GI at the proximal jejunum AND in order to meet USP requirements for folic acid dissolution and disintegration; it is* ***patent pending. CitraFolic® uses only DMF-approved manufacturers of folic acid.***

¶ ***AminoFerr®*** *as ferrous glycine cysteinate, also known as FERROUS CYSTEINE GLYCINATE, and has the Unique Ingredient Identifier (UNII) code 8B4OP7RK5N. AminoFerr® is a proprietary ingredient containing pure chelates without interfering ions -resulting in high solubility and absorption; it is the only pure amino acid iron chelate supplement on the market, and is protected under US Patent No. 7,341,708.*

Zinc-NACx® *as zinc n-acetyl-l-cysteine also known as ACETYLCYSTEINE ZINC, and has the UNII code LP811J9FA1. Zinc-NACx® is* ***a patent pending*** *amino-acid derivative chelate of zinc; It uses the proprietary NACx®-technology - which is the world's first amino-acid derivative chelate. It was co-developed by Via Naturally, LLC and Viva Pharmaceuticals (Richmond, BC, Canada).*

Þ Daily Value not established ~Approximate value

OTHER INGREDIENTS

Coating (FD&C Yellow No. 6 Lake, FD&C Blue No. 2 Lake, hydroxypropyl methylcellulose, polyethylene glycol, polyvinyl alcohol, titanium dioxide, talc), croscarmellose sodium, magnesium stearate, microcrystalline cellulose, piperine[1], pregelatinized starch, silicified microcrystalline cellulose, silicon dioxide, stearic acid..... *[and other ancillary ingredients[2] as needed to ensure product stability]*…

This product contains FD&C Yellow #6 Lake.

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1 *Bioavailability enhancer piperine as BioPerine® is a registered trademark of Sabinsa Corporation, Piscataway, NJ. Protected and manufactured under US Patent Nos. 5,536,506, 5,744,161, 5,972,382; and 6,054,585.*

2 *Since additives, preservatives, bioavailability enhancers, colors and/or flavors of natural origin, etc. are preferred over synthetics, it may be the case that product color, appearance and/or taste may vary slightly over time; and it may be necessary to substitute excipients during the manufacturing process as needed to preserve product appearance and continuity in order to avoid confusion in the marketplace and ensure the highest therapeutic target, safety and quality.*

ALLERGY STATEMENT

This product has been manufactured in a facility that also manufactures products containing tree nuts, peanuts, fish, egg, wheat, milk, soy and shellfish. Individuals with allergic tendencies to these substances should use discretion.

CONTRAINDICATIONS

DermaNIC™ is contraindicated in patients with a known hypersensitivity to any of the components contained in this product. **DermaNIC™** is contraindicated for individuals with conditions for which any

of the **DermaNIC™** ingredients are contraindicated.

INTERACTIONS

Talk to your healthcare practitioner and/or pharmacist before taking or using any prescription or over-the-counter medicines or herbal/health supplements alongside **DermaNIC™**.

This product should not be taken at the same time as tetracycline because it may interfere with the absorption and effectiveness of the antibiotic. This product should be taken at different times of the day, at least two hours apart, from tetracycline.

WARNINGS

This product contains iron.

Warning: Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. Keep this product out of the reach of children. In case of accidental overdose, call a doctor or poison control center immediately.

Extreme caution should be used when prescribing this product to patients with a history of liver disease, jaundice, diabetes and/or kidney disease. These patients, as well as patients with a history of heavy use of alcohol, gallbladder disease, gout, and/or stomach ulcers, should be monitored closely. Abnormal liver functions tests have been reported in persons taking high doses of niacin. Patients with coronary artery disease or unstable angina should not take niacin without their licensed medical practitioner's supervision, as large doses can increase the risk of heart rhythm problems. Caution is also advised in patients with low blood pressure as niacin may cause a dangerous drop in blood pressure. Niacin can be toxic to the liver at high doses. Do not exceed 3 grams per day of nicotinamide.[1] Do not use other niacin-containing products while taking this product unless under the supervision of a licensed healthcare practitioner. This product is not formulated or intended to be used to treat hyperlipidemias. This product contains four different forms of niacin as Quadracin™, with the majority of the niacin being supplied in slowly metabolized forms, such as nicotinamide and inositol nicotinate. Nicotinamide does not have the same lipid modifying effects as nicotinic acid.

Caution is recommended in patients taking anticonvulsant medications as folate may interfere with anticonvulsant medication, and may lower seizure threshold. Furthermore, it has been reported that anticonvulsant medications interfere with folate metabolism, but the exact action is unclear; therefore caution is recommended with patients in this therapeutic group.

Patients undergoing cancer treatment should consult their licensed medical practitioner for advice. Before having surgery, tell your licensed medical practitioner that you are taking this product.

PRECAUTIONS

Folate alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where vitamin B_{12} is deficient. Folate in doses above 0.1 mg daily may obscure pernicious anemia in that hematologic remission may occur while neurological manifestations progress.

ADVERSE REACTIONS

"Niacin flush" is a burning, tingling sensation in the face and chest, and red or flushed skin and is associated with rapidly metabolized niacin[3]. This reaction usually goes away as the body gets used to the medication. Other side effects of niacin include stomach upset, intestinal gas, dizziness, and pain in the mouth. Allergic reactions have been reported following the use of oral and parenteral folate. Mild transient diarrhea, polycythemia vera, itching, transitory exanthema and the feeling of swelling of the

entire body has been associated with cobalamin. **Call your medical practitioner about side effects. You may report side effects by calling 1-866-633-9033.**

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[3] ***DermaNIC™*** *is formulated primarily with slowly metabolized niacin vitamers that present a lower risk of flushing than rapidly metabolized forms. Nevertheless, some patients may want to titrate slowly to the maintenance level as prescribed by a licensed medical practitioner.*

PHARMACOLOGY

NIACIN

Niacin, or vitamin B_3, is a water-soluble vitamin absorbed in the stomach and upper small intestine, and refers to both nicotinic acid and niacinamide. Niacin circulates in the plasma as nicotinic acid and nicotinamide. It is biosynthetically converted into nicotinamide adenine dinucleotide (NAD+) and the phosphorylated dinucleotide nicotinamide adenine dinucleotide phosphate (NADP+). NAD and NADP are coenzymes in a wide variety of enzymatic oxidation-reduction reactions. The antioxidant enzyme glucose-6-phosphate dehydrogenase (G6PD) maintains the level of NADPH which is important for glutathione production. However, G6PD activity has been shown to be low in some acne patients.[22] **DermaNIC™** provides niacin as Quadracin™ which contains:

NICOTINAMIDE

Nicotinamide is the amide derivative of nicotinic acid, and is provided as niacinamide. *In vivo*, nicotinamide is incorporate into nicotinamide adenine dinucleotide (NAD) and nicotinamide adenine dinucleotide phosphate (NADP). Nicotinamide has been shown to have anti-inflammatory activities, and has been shown to inhibit lipopolysaccharide-induced TNF-alpha in a number of animal studies. It is thought that this inhibition of TNF-alpha is mediated via inhibition, at the gene transcription level, of NF-Kappa B, which in turn inhibits TNF-alpha. Nicotinamide has also been shown to decrease the production of IL-12 and TNF-alpha in cultures of whole blood from prediabetic and diabetic subjects and also in healthy subjects.

NICOTINIC ACID

Nicotinic acid is an essential dietary constituent, the lack of which leads to pellagra, a condition characterized by an erythematous skin eruption as well as gastrointestinal and neurological symptoms. Nicotinic acid is converted to nicotinamide *in vivo*. Recent studies suggest that nicotinic acid may inhibit vascular oxidative stress, redox-sensitive genes and monocyte adhesion to human aortic endothelial cells; implying that nicotinic acid inhibits vascular inflammation and has antiatherosclerotic properties independent of, and in addition to, its lipid-modulating effects. Studies have shown that the cutaneous vasodilation nicotinic acid induces - resulting in the so-called "niacin flush" that is harmless but causes some patients discomfort and prevents them from continuing to use nicotinic acid, likely subsides after a couple of doses and/or continued use. Also included in this formulation are two niacin derivative conjugates: 1) INOSITOL NICOTINATE - Inositol nicotinate is a conjugated derivative of nicotinic acid that appears to be slowly metabolized, and therefore is less likely to cause flushing while still delivering the nicotinic acid moiety with the added benefit of inositol; and 2) CHROMIUM POLYNICOTINATE - Chromium polynicotinate is another nicotinic acid derivative conjugate that delivers the nicotinic acid moiety with the added benefit of chromium.

ZINC

The zinc in this product is supplied as Zinc-NACx®, which also provides the glutathione precursor n-acetyl-cysteine (NAC). Zinc plays a role in the folate cycle via the zinc metalloenzyme betaine homocysteine methyl transferase (BHMT). In addition, the antioxidant enzyme superoxide dismutase (SOD) requires zinc as a cofactor. Zinc acts on inflammatory cells, especially granulocytes.[2] Studies show that oxidative stress exists in acne patients.[21] Zinc levels have been reported to be low in patients

with acne.

PHARMACOLOGICAL COFACTOR-INGREDIENTS

IRON

DermaNIC™ supplies iron as pure amino acid iron-chelate, which provides pure elemental iron - an essential component in the formation of hemoglobin. Iron therapy is necessary in advanced folate supplementation due to interference between iron and folate metabolism.[6] Sufficient amounts are required for effective erythropoiesis. The selection of a non-heme form of supplemental iron is also important because the heme carrier protein (HCP) has been demonstrated also to be a proton coupled folate transporter (PCFT).[6] As a result, when dietary folate intake is high, as would be with the administration of **DermaNIC™**, heme iron transport can be sacrificed, leading to potential iron deficiency. Co-administering non-heme iron compensates for these potential metabolic imbalances. This proprietary form of iron is protected under US Patent No. 7,341,708.

COBALAMIN

Cobalamin is required for two important reactions: the conversion of methylmalonyl CoA to succinyl CoA, a Krebs cycle intermediate, and the conversion of homocysteine to methionine, a reaction in which the methyl group of methyltetrahydrofolate is donated to remethylate homocysteine.[16] Many factors contribute to the cobalamin deficiency including diet, gastrointestinal pathology, autoimmune disease and medications.

BIOAVAILABILITY ENHANCER

Piperine is an alkaloid found naturally in plants, and may have bioavailability-enhancing activity for some nutritional substances and for some drugs.[7]

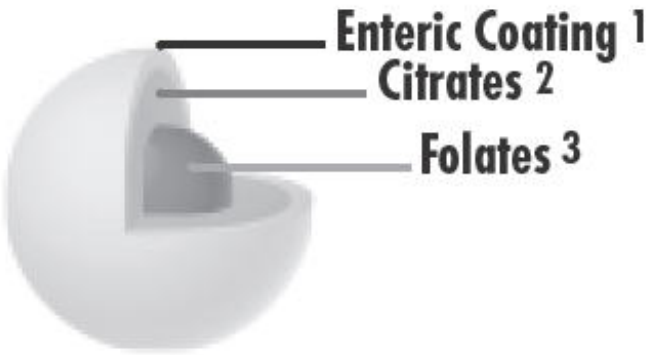
FOLATE

Folates are best known for reducing the incidence of fetal neural tube defects (NTDs).[24-26] NTDs are congenital malformations produced by failure of the neural tube to form and close properly during embryonic development.[17,25] During the first four weeks of pregnancy - when many women do not even realize that they have conceived, adequate maternal folate intake is essential to reduce the risk of NTDs. As the postnatal period approaches there is increased demand again for folate regardless of lactation status. Folate is involved in transformylation and methylation metabolism as well as - indirectly, succinylation metabolism (through the "methyl trap" hypothesis). Folate plays a central role in the formation of nucleic acid precursors, such as thymidylic acid and purine nucleotides, which are essential for nucleic acid synthesis and cell division. IOM/NAS (1998) noted that the evidence for a protective effect from folate supplements is much stronger than that for food folate.[17] Other dietary ingredients are added to folate as cofactors, coenzymes and co-metabolites; in studies by Czeizel and Dudas (1992) and Berry et al. (1999), factors other than folate may affect the magnitude of risk reduction or participate in a co-protective effect with folate. The need for folate for methyl group biosynthesis may also increase with high niacin intake. The major pathway of metabolism of nicotinamide is by methylation in the liver to form N-methylnicotinamide via reaction with methionine (as a methyl donor) and ATP. As a result, high levels of niacin may interfere with the metabolism of methionine, which could lead to hyperhomocysteinemia. Increased folate intake may also confer a protective effect against folate depletion and subsequent hyperhomocysteinemia in acne patients taking antibiotics.[18-20] Certain antibiotics may affect the absorption and metabolism of folate. Isotretinoin, for example, has been shown to decrease serum folic acid levels.[18] Furthermore, studies have reported elevated plasma homocysteine in patients on isotretinoin as quickly as 45 days after beginning therapy.[19] Isotretinoin may inhibit the activity of the cystathionine-beta-synthase enzyme, thereby impairing the conversion of homocysteine to cystathionine in the transsulfuration pathway. Furthermore, one of the most common antibiotic treatments for acne includes the Sulfa antibiotics - such as cotrimoxazole, that

inhibits folic acid synthesis in bacteria. This highlights the importance of folic acid, or folate, rescue therapy as an adjunctive modality to be used in the treatment of acne alongside traditional acne drug therapy. Additionally, serum folate levels were decreased in post adolescent acne patients.[23]

The present form of folate in this product is:

FOLIC ACID as CitraFolic®[4] is a novel, controlled-release delivery method to optimize absorption of folic acid. CitraFolic® uses proprietary technology to encapsulate conventional folic acid, along with citrates, in controlled-release pellets. CitraFolic® is unique from conventional folic acid in that it: 1.) complies with USP requirements for folic acid dissolution. Some studies indicate that dissolution failure - that is, the failure of conventional folic acid supplements to meet USP requirements for dissolution - is a significant, concerning problem.[4] 2.) includes buffers to adjust the pH in order to remain soluble in a high acid environment, such as the gastric environment. This is important because folic acid must remain soluble in the acidic environment of the stomach in order to be absorbed in the intestine. Studies show that solubility of conventional folic acid decreases with increased acidity.[5] Folic acid is converted into functional, metabolically active coenzyme forms for use in the body (61 Fed. Reg. at 8759-60), and supplies the active folate substrate, THF (tetrahydrofolate).[16,17,24-26] Because the folate is controlled release (enteric coating delays 20 minutes then not less than 90% of folate is dissolved according to United States Pharmacopeia (USP) specifications within 60 minutes), it is less likely to interfere with heme iron (hemoglobin-derived iron) absorption as the body's transport has a greater affinity for folic acid than for heme iron.[6]



1. Enteric coating creates an initial delayed release of approximately 20 minutes, non-pH-dependant, in order to aid in reducing first pass metabolism degradation, high-acidity environmental exposure and/or oxidation factors.
2. Citrates are dispersed in a 2:1 ratio of sodium citrate to citric acid in order to achieve optimum pH for folic acid dissolution as per USP specifications.
3. Folates are dispersed amongst the citrates in a 1:3 ratio of folic acid to citrates in order to reach maximum dissolution potential in variant mediums.

Note: The total folate-citrate matrix reaches 75% dissolution between the first 20 to 45 minutes, with over 90% folate dissolution achieved - as per USP, within 60 minutes.

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4 *CitraFolic® uses only DMF-approved manufacturers of folic acid.*

MECHANISM OF ACTION

NIACIN is an essential coenzyme in a wide variety of enzymatic oxidation-reduction reactions.[24-26] ZINC is required for a number of immune functions, including T-lymphocyte activity. Zinc supplementation can restore impaired immune function in those with zinc deficiency, as found in malabsorption syndromes and acrodermatitis enteropathica.[26] IRON is necessary for the production of

hemoglobin. Iron-deficiency can lead to decreased production of hemoglobin and a microcytic, hypochromic anemia and/or megaloblastic anemia.[26] FOLATE is essential for the production of certain coenzymes in many metabolic systems such as purine and pyrimidine synthesis. It is also essential in the synthesis and maintenance of nucleoprotein in erythropoiesis. It also promotes white blood cell (WBC) and platelet production in folate-deficiency anemia. Folate is associated with methylation and transformylation biochemistry.[16,24-26]

FOLATE (R_X) REGULATION

The Federal Register Notices from 1971 to 1973 established that increased folate was proper therapy in megaloblastic anemias of tropical and nontropical sprue, nutritional origin, pregnancy, infancy and childhood.[10-13] Folate metabolism can be affected by malabsorption issues which differ widely among population groups. The March 5, 1996 Federal Register Notice (61 FR 8760) states that "The agency concluded that ***the scientific literature did not support the superiority of any one source of folate over others, and that the data were insufficient to provide a basis for stating that a specific amount of folate is more effective than another amount***."[16] The actual amount and source of folate require a licensed medical practitioner's supervision to achieve a satisfactory maintenance level, and may exceed the 0.8 mg UL. The Federal Register Notice of August 2, 1973 (38 FR 20750) specifically states that "dietary supplement preparations are available without a prescription (21 CFR 121.1134). ***Levels higher than dietary supplement amounts are available only with a prescription. Oral preparations supplying more than 0.8 mg of folate per dosage unit would be restricted to prescription dispensing*** and that a dietary supplement furnishing 0.8 mg could be prescribed when a maintenance level of 0.8 mg per day was indicated. When clinical symptoms have subsided and the blood picture and/or CSF folate levels have become normal, a maintenance level should be used. Patients should be kept under close supervision and adjustment of the maintenance level made if relapse appears imminent. In the presence of alcoholism, hemolytic anemia, anticonvulsant therapy, or chronic infection, the maintenance level may need to be increased."[11] However, once the level of active folate exceeds 0.8 mg - as prescribed dosages, then the product is no longer a medical food but a **prescription dietary supplement** regardless of pregnancy/lactation status in spite of the fact that folic acid - including reduced forms, may be added to medical foods as defined in section 5(b)(3) of the Orphan Drug Act (21 USC 360ee(b)(3)), or to food (21 CFR 172.345).[14-15] In the Letter Regarding Dietary Supplement Health Claim for Folic Acid, Vitamin B_6, and Vitamin B_{12} and Vascular Disease (Docket No. 99P-3029) dated November 28, 2000, FDA wrote "... high intakes of folate may partially and temporarily correct pernicious anemia while the neurological damage of vitamin B_{12} deficiency progresses. IOM/NAS (1998) set the UL for all adults of 1 mg per day because of devastating and irreversible neurological consequences of vitamin B_{12} deficiency, the data suggesting that ***pernicious anemia may develop at a younger age in some racial or ethnic groups, and the uncertainty about the extent of the occurrence of vitamin B_{12} deficiency in younger age groups*** (IOM/NAS, 1998)."[16] Summary: This product is a dietary supplement product that - due to advanced folate levels, requires administration under the care of a licensed medical practitioner, and the most appropriate way to do that is to provide the product as prescription for pedigree reporting and safety monitoring. The ingredients, indication or claims of this product are not to be construed to be drug claims.

PATIENT INFORMATION

DermaNIC™ is a prescription dietary supplement to be used only under licensed medical supervision. Your licensed medical practitioner may choose to prescribe **DermaNIC™** along with other medications.

PREGNANCY AND NURSING MOTHERS

DermaNIC™ contains a high dose of niacin and is **NOT** recommended for pregnant and/or lactating women. However, **DermaNIC™** can be administered to women of childbearing age.

INDICATIONS AND USAGE

DermaNIC™ is indicated for the distinct nutritional requirements of individuals undergoing acne therapy who require advanced niacin and/or zinc supplementation. **DermaNIC™** is not a drug, but may be used as monotherapy[5] ("rescue" therapy) or adjunctive therapy as determined by your licensed medical practitioner. The adjunctive use of **DermaNIC™** enables medical practitioners to combine therapeutic modalities (dietary management and drug therapy). The multifactorial etiologies of acne (i.e., hyperkeratinization, increased sebum, P. acnes, and inflammation) as well as the prevention of bacterial resistance all facilitate the need for new developments in combination acne therapy. Combining agents that target the different etiological factors of acne can help increase efficacy and response time.

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5 *In patients with suboptimal folate levels - and as determined by your licensed medical practitioner, **DermaNIC™** may be administered as rescue or adjunctive folate-therapy to provide a protective effect in reducing the risk of secondary/endpoints and/or disease-states of hyperhomocysteinemia such as may be found with isotretinoin acne therapy. Folate is effective in the treatment of hyperhomocysteinemia and/or megaloblastic anemias[8] (as may be seen in tropical or nontropical sprue) and in anemias of nutritional origin,[24-26] pregnancy,[17] infancy, childhood or other related folate-malabsorption complications of an inborn or environmental origin.[9]*

DOSAGE AND ADMINISTRATION

Take 1 (one) tablet once or twice daily or as prescribed by a licensed medical practitioner[6]. **DermaNIC™** should be taken with food. **Do not take at the same time as a tetracycline antibiotic.**

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6 *Tablet may be split in half in order to titrate the dosage level. To titrate the medication is to start by taking a low dose of medicine then to gradually increase the dosage to the required level. Titration helps in reducing the side effects of medicine as it allows the body to first adapt to the medication.*

HOW SUPPLIED

DermaNIC™ is supplied as a scored, beige-colored, oval tablet debossed with "044" on one side, in bottles of 60 tablets, (Product Code[7]28595-500-60). **DermaNIC™** is also supplied to licensed healthcare practitioners as 1ct samples, 28595-500-99. ***DermaNIC™ may - under certain circumstances, be dispensed through a certified mail-order program so long as there is record of prescription AND confirmation that the patient is under licensed medical supervision.***

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7 *This product is a prescription-folate with or without other dietary ingredients that - due to increased folate levels (AUG 2 1973 FR 20750), requires an R_x on the label because of increased risk associated with masking of B_{12} deficiency (pernicious anemia). Based on our assessment of the risk of obscuring pernicious anemia, this product requires licensed medical supervision, an R_x status, and a National Drug Code (NDC) - or similarly- formatted product code, as required by pedigree reporting requirements and supply-chain control as well as - in some cases, for insurance-reimbursement applications. **This product is not an Orange Book (OB) rated product, therefore all prescriptions using this product shall be pursuant to State statutes as applicable.***

STORAGE

Store at room temperature 20° to 25° C (68° to 77° F). Dispense in a tight, light-resistant container. Protect from light and moisture.

KEEP THIS PRODUCT OUT OF REACH OF CHILDREN.

MADE IN CANADA.
R_x

MANUFACTURED FOR: Allegis Pharmaceuticals, LLC, Canton, MS 39046.

PATENTS: US Patent Nos. 7,341,708, 5,536,506, 5,744,161, 5,972,382; and 6,054,585. Other patent applications pending.

TRADEMARKS: ***DermaNIC™*** *is a trademark of Allegis Pharmaceuticals, LLC (Canton, MS, USA).* ***DermaNIC™*** *was developed by Captiva Pharma, LLC (Fort Myers, Florida, USA).* ***Zinc-NACx®*** *and* ***CitraFolic®*** *are registered trademarks of Via Naturally, LLC (Fort Myers, Florida, USA).* ***AminoFerr®*** *is a registered trademark of Viva Pharmaceuticals (Richmond, BC, Canada).* ***Quadracin™*** *is a use-trademark of Captiva Pharma, LLC.*

REVISION: January 2014

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PRINCIPAL DISPLAY PANEL - 60 Tablet Bottle Label

28595-500-60

DermaNIC™
with Quadracin™

PRESCRIPTION (R_x) DIETARY SUPPLEMENT
MULTIPHASIC TABLETS

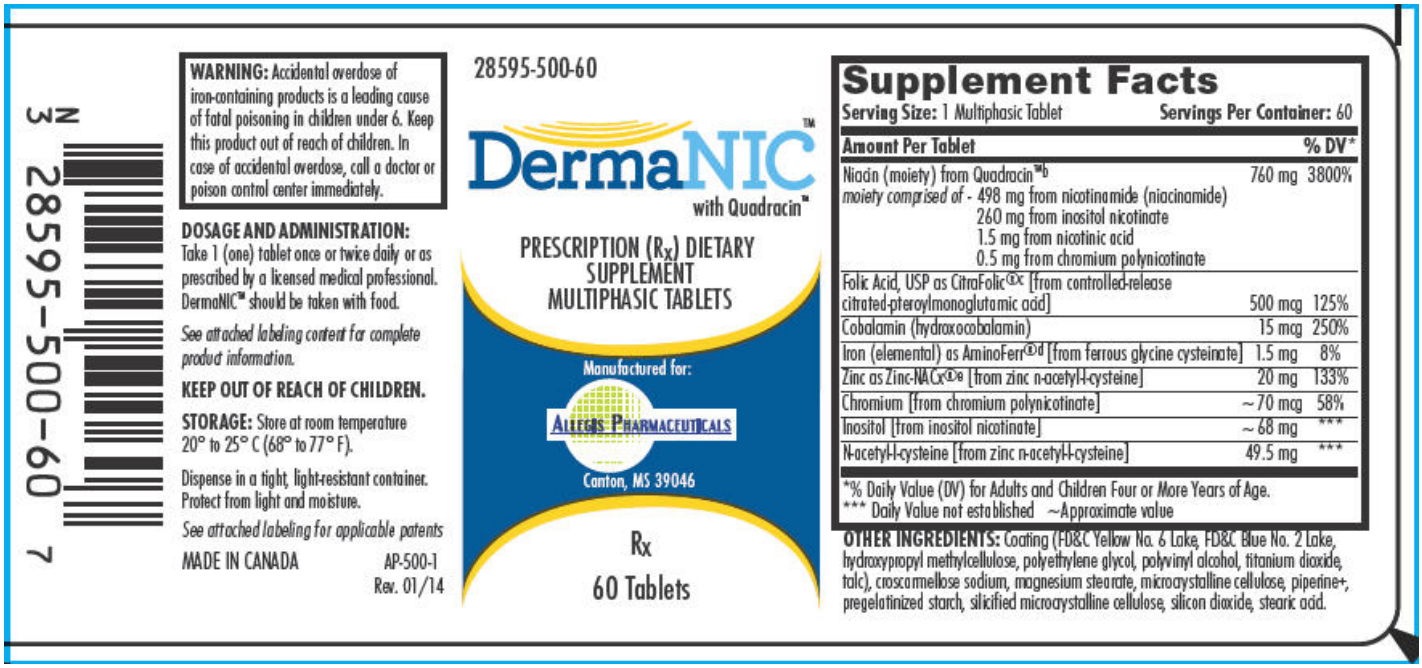
Manufactured for:

ALLEGIS PHARMACEUTICALS

Canton, MS 39046

R_x

60 Tablets



DERMANIC

niacinamide, inositol niacinate, niacin, chromium nicotinate, folic acid, hydroxocobalamin, ferrous cysteine glycinate, and acetylcysteine zinc tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:28595-500

Route of Administration	ORAL	**DEA Schedule**	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NIACINAMIDE (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	498 mg
INOSITOL NIACINATE (UNII: A99MK953KZ) (NIACIN - UNII:2679MF687A, INOSITOL - UNII:4L6452S749)	INOSITOL NIACINATE	328 mg
NIACIN (UNII: 2679MF687A) (NIACIN - UNII:2679MF687A)	NIACIN	1.5 mg
CHROMIUM NICOTINATE (UNII: A150AY412V) (NIACIN - UNII:2679MF687A, CHROMIC CATION - UNII:X1N4508KF1)	CHROMIUM NICOTINATE	0.57 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	500 ug
HYDROXOCOBALAMIN (UNII: Q40X8H422O) (HYDROXOCOBALAMIN - UNII:Q40X8H422O)	HYDROXOCOBALAMIN	15 ug
FERROUS CYSTEINE GLYCINATE (UNII: 8B4OP7RK5N) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	1.5 mg
ACETYLCYSTEINE ZINC (UNII: LP811J9FA1) (ZINC CATION - UNII:13S1S8SF37, ACETYLCYSTEINE - UNII:WYQ7N0BPYC)	ACETYLCYSTEINE ZINC	69.5 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TALC (UNII: 7SEV7J4R1U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
PIPERINE (UNII: U71XL721QK)	
STARCH, CORN (UNII: O8232NY3SJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	BROWN (beige)	**Score**	2 pieces
Shape	OVAL	**Size**	20mm
Flavor		**Imprint Code**	044
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:28595-500-60	60 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		02/03/2014	

Labeler - Allegis Pharmaceuticals, LLC (792272861)

Revised: 2/2014 Allegis Pharmaceuticals, LLC